

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Original) A cartridge for determining the presence or amount of a microbial contaminant in a sample, the cartridge comprising:
 - (i) a housing defining a fluid inlet port, an optical cell, and a conduit having a fluid contacting surface for providing fluid flow communication between the fluid inlet port and the optical cell; and
 - (ii) hemocyte lysate disposed on a region of the fluid contacting surface of the conduit, so that when a sample is applied to the fluid inlet port, the sample traverses the region and solubilizes the hemocyte lysate during transport to the optical cell.
2. (Original) The cartridge of claim 1, further comprising a chromogenic substrate disposed on a second region of the fluid contacting surface.
3. (Original) The cartridge of claim 2, wherein the second region is downstream of the first region.
4. (Original) The cartridge of claim 1, further comprising a preselected amount of an agent representative of the microbial contaminant disposed on the fluid contacting surface of the conduit.
5. (Original) The cartridge of claim 4, wherein the agent is disposed on the first region.
6. (Original) The cartridge of claim 4, wherein the agent is a bacterial endotoxin or a (1→3)-β-D glucan.
7. (Original) A cartridge for determining the presence or amount of a microbial contaminant in a sample, the cartridge comprising:

(i) a housing defining

a first fluid inlet port, a first optical cell, and a first conduit having a fluid contacting surface for providing fluid flow communication between the first fluid inlet port and the first optical cell, and

a second fluid inlet port, a second optical cell, and a second conduit having a fluid contacting surface for providing fluid flow communication between the second fluid inlet port and the second optical cell;

(ii) a first hemocyte lysate disposed on a first region of the fluid contacting surface of the first conduit, so that when a sample is applied to the first fluid inlet port, the sample traverses the region and solubilizes the first hemocyte lysate during transport to the first optical cell; and

(iii) a second hemocyte lysate disposed on a first region of the fluid contacting surface of the second conduit, so that when sample is applied to the second fluid inlet port, the sample traverses the region and solubilizes the second hemocyte lysate during transport to the second optical cell.

8. (Original) The cartridge of claim 7, further comprising a chromogenic substrate disposed on a second region of the fluid contacting surface of the first conduit.

9. (Original) The cartridge of claim 8, wherein the second region is downstream of the first region.

10. (Original) The cartridge of claim 8, further comprising a chromogenic substrate disposed on a second region of the fluid contacting surface of the second conduit.

11. (Original) The cartridge of claim 10, wherein the second region is downstream of the first region.

12. (Original) The cartridge of claim 7, further comprising a preselected amount of an agent representative of a microbial contaminant disposed on the fluid contacting surface of the first conduit.

13. (Original) The cartridge of claim 12, wherein the agent is disposed on the first region.

14. (Original) The cartridge of claim 12, wherein the agent is a bacterial endotoxin or a (1→3)-β-D glucan.

15. (Currently amended) A method of detecting the presence of a microbial contaminant in a sample, the method comprising the steps of:

(a) introducing a sample into the sample inlet port of the cartridge ~~of any one~~ of claims 1-6;

(b) permitting the sample to move to the optical cell; and

(c) measuring an optical property of the sample in the optical cell, wherein a change in the optical property is indicative of the presence of a microbial contaminant in the sample.

16-17. (Cancelled)

18. (Currently amended) A method of determining the amount of a microbial contaminant in a sample, the method comprising the steps of:

(a) introducing a sample into the sample inlet port of the cartridge ~~of any one~~ of claims 1-6;

(b) permitting the sample to move to the optical cell;

(c) measuring the time in which a preselected change occurs in an optical property of the sample in the optical cell; and

(d) comparing the time measuring in step (c) against a predetermined standard curve to determine the amount of the microbial contaminant in the sample.

19-20. (Cancelled)

21. (Original) A method of determining the presence of a microbial contaminant in a sample, the method comprising the steps of:

(a) contacting a sample with a hemocyte lysate comprising an activatable enzyme to produce a sample-lysate mixture, whereupon the enzyme becomes activated if the microbial contaminant is present in the sample;

(b) after step (a), contacting the sample-lysate mixture with a substrate for the enzyme to produce a sample-lysate-substrate mixture, such that, if the mixture contains activated enzyme, the activated enzyme produces a change in the substrate;

(c) determining the time in which a preselected change occurs in an optical property of the sample-lysate-substrate mixture, wherein the change in optical property results from a change in the substrate; and

(d) comparing the time determined in step (c) against a predetermined standard curve to determine whether the contaminant is present in the sample.

22-43. (Cancelled)

44. (Original) A method of drying a hemocyte lysate onto a solid support, the method comprising the steps:

(a) applying a volume of a mixture comprising a hemocyte lysate, a resolubilizing agent and an anti-flaking agent to the surface of a solid support; and

(b) drying the mixture onto the solid support.

45-58. (Cancelled)

59. (Original) A method of preparing an amebocyte lysate depleted of Factor C activity, the method comprising:

(a) providing a preparation of amebocytes; and

(b) lysing the amebocytes in the presence of at least 0.15 M salt to provide an amebocyte lysate preparation depleted of Factor C activity.

60-69. (Cancelled)

70. (Original) An amebocyte lysate substantially free of Factor C activity, wherein the lysate comprises at least about 0.25 M salt, and wherein the lysate is capable of reacting with glucan to produce a coagulin gel.
- 71-76. (Cancelled)
77. (Original) A manufacture comprising a solid support having dried thereon a composition comprising a hemocyte lysate and (i) an anti-flaking agent, (ii) an anti-frothing agent, (iii) a resolubilizing agent, (iv) an anti-flaking agent and an anti-frothing agent, (v) an anti-flaking agent and a resolubilizing agent, (vi) an anti-frothing agent and a resolubilizing agent, or (vii) an anti-flaking agent, an anti-frothing agent and a resolubilizing agent.
78. (Cancelled)